REMARKS

This Reply is in response to the Office Action mailed on June 13, 2007 (Office Action). In the Office Action, claims 1-10 are withdrawn from consideration and claims 11-38 are rejected. In this reply claims 15-29 have been amended to recite "The composite of claim 11," rather than "The composition of claim 11". New dependent claims 39-44 are presented. The new claims are directed to the sol-gel derived glass and the nature of its disposition in the composite of the present invention. Support for new claims 39 and 40 is found in paragraphs [0060] through [0067] and Fig. 7 of the specification.

With regard to claim rejections in light of cited references:

Examiner states:

3. Claims 11,13-17,21,23,24,26-30,32,34,36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al (USPN 6,294,041 hereafter '041). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

4. The '041 patent teaches an osteoimplant comprising calcium phosphate, active agents and other common ingredients (abstract). The implant comprises bioabsorbable polymers and excipients such as starches, polymethyl methacrylates, polyethylene and other common polymers (col. 4, lin. 25-40). The implant further comprises bioactive compounds such as antiviral agents,

and biological compounds such as stem cells and collagen, along with various growth factors (col. 4, lin. 60-col. 5, lin. 15). The implant is applied to an injured or defective area in order to repair the effected area (col. 5, lin. 65-col. 6, lin. 25). The collagen is surface bonded to the implant (col. 6, lin. 26-35). The composition is present in various forms including fibers (example 1). Theses disclosures render the claims anticipated.

Applicants respectfully disagree with the view that '041 anticipates any claim of the present invention. The abstract of '041 does not disclose "an osteoimplant comprising calcium phosphate, active agents and other common ingredients" as indicated by the Examiner. Rather '041 discloses "an osteoimplant fabricated from a solid aggregate of bone derived elements possessing chemical linkages between their adjacent surface-exposed collagen", (see '041 Abstract) which differs significantly from the composites of the present invention where no bone-derived elements are present. Furthermore, '041 discloses that "In order to expose the collagen located on the outer surface of bone, the bone elements must be at least partially demineralized. Demineralization methods remove the mineral component of bone employing acid solutions." (see '041 col. 3 lines 53-57) Hence, although the osteoimplant from bone-derived elements of '041 can tolerate bone minerals, presumably including the calcium phosphate of hydroxyapatite, it is the removal of such minerals at the surfaces to interact with the body and each other that enables the invention a feature that teaches away from the necessity for calcium and phosphate species to be present in the glass of the present claimed invention. In a large proportion of the osteoimplants disclose it is required or desired that the bone-derived material be completely demineralized. (see '041 claims 6, 15, 30, 35, 44, and 47 and 14, 27, 36, 43, and 52) Furthermore, '041 does not disclose a true glass to be present even optionally as the "bioglass or other bioceramic" (see '041 col. 4 lines 31-32) identifies bioglass as a ceramic, while the present invention is directed to true glasses, as is commonly known in and outside of the art according to Merriam-Webster Online Dictionary:

> glass 1: any of various **amorphous materials formed** from a melt by cooling to rigidity **without crystallization**: as a: a usually transparent or translucent material consisting typically of a mixture of silicates b: a material (as obsidian) produced by fast cooling of magma. (emphasis added) (http://www.m-w.com/dictionary/glass)

The present invention is particularly directed to a sol-gel derived glass, which lack crystallinity (see Fig. 7, curve a, present application) in contrast to ceramics, including commercially available bioglasses, which have crystalline content. Because '041 has the requirement of demineralized bone-derived material and does not disclose any option of a true glass in the composition, '041 can not anticipate the present claimed invention that requires a biocompatible polymer and a bioactive glass including at least one calcium, and at least one phosphorous molecular species in the composite as in claim 11-29 or methods where a glass or glass precursor is included as in claims 30-38. Applicants respectfully request allowance of claims 11, 13-17, 21, 23, 24, 26-30, 32, 34, 36 and 37.

Examiner states:

5. Claims 11-14,26,27,28,30,31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (USPN 6,027,742 hereafter '742). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

6. The '742 patent teaches a bioresorbable ceramic composite comprising calcium phosphate and other materials (abstract). The composite comprises collagen, demineralized bone and other natural material I (col. 9, lin. 45-48) as well as polymers such as polyesters of carboxylic acids (col. 9, lin. 50-55). The further includes harvested cells that are seeded into the implant and proliferate at the implantation site (col. 12, lin. 10-22). The composites are formed by well-known methods including mixing, blending and alloying (col. 13, lin. 62-65). The particles produced range in size from 25-200 microns (example 6). These disclosures render the claims anticipated.

Applicants respectfully disagree that '742 entitled "Bioresorbable Ceramic Composites" can anticipate a non-bioresorbable non-ceramic composite such as the present invention of claim

11, which is a glass composite that does not display crystallinity. The calcium and phosphate material of '742 must specifically be a "poorly crystalline apatitic (PCA) calcium phosphate cement having an x-ray diffraction pattern" (see '742 claim 1) and although "The PCA material is not necessarily restricted to a single calcium phosphate phase provided it has the characteristic XRD and FTIR pattern. A PCA calcium phosphate has substantially the same X-ray diffraction spectrum as bone." (see '742 col. 6 lines 17-20). Again, the necessity of some crystallinity and the specific crystalline X-ray diffraction spectrum of bone, as disclosed in '742, is in contrast to the glass composite of the present invention where the bioactive composite can promote the formation of hydroxyapatite crystals when exposed to an appropriate biological fluid or its synthetic equivalent, but does not have evidence of crystallinity prior to exposure of the composite to the fluid. (see Fig. 5, Fig 7 of present application). As '742 does not teach the glass of the present invention but rather a ceramic, and specifically requires that the ceramic is a poorly crystalline apatitic (PCA) calcium phosphate, the present invention is not anticipated by '742. Applicants respectfully request that claims 11-14, 26, 27, 28, 30, 31, and 34-36 be allowed.

Examiner states:

7. Claims 11,12,17-19,30,33,36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Marotta et al (USPN 5,990,380 hereafter '380). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The composite comprises fibers that are equally spaced. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

8. The '380 patent teaches a bioglass implant comprising calcium and phosphate molecules in a composite with others compounds (abstract, table 1). The particles are below 100 microns (col. 6, lin. 5-12) and are present in fibers that are spaced from 20-200 microns apart (claims, examples). The composite is formed at room temperature by mixing the components (examples). These disclosures render the claims anticipated.

Applicants respectfully disagree with the characterization of the material of '380 which has a "dermal bonding region including a substrate with a discontinuous coating of particulate bioactive glass wherein the average spacing between the particles of bioactive glass" (see '380 abstract) as being the composite of the present application. In '380, the "bioactive component of the present invention includes a discontinuous layer of particles or fibers on the outer surface of a substrate. Interference with the flexible nature of the substrate is minimized and cracking of the bioactive layer is avoided because the particles or fibers are discrete and are free to flex with the underlying substrate". (see '380 col. 4 lines 30-35) The substrate is disclosed to be a silicone elastomer upon which an uncured silicone elastomer is spread as a thin film where glass particles or small fibers are deposited through the voids of a mesh to leave a patterned coating after removal of particles not deposited in the uncured elastomer and the mesh after curing takes place in the uncured elastomer to lock the particles on the surface as an evenly space discontinuous coating of particles on a face of the substrate. (see '380 Example 2) The present invention does not teach a deposition of glass particles on a specific face with a specific pattern. Rather the present invention uses a polymer which has been mixed with a glass precursor, to form a sol solution, which leads to a co-continuous dispersion of the polymer with the glass fixing the composite by the inorganic network upon gelation. (see paragraph [0060] of the present application) Although the present invention can be used as a coating, the disposition of the bioactive glass in the composite is not as a coating, particularly as a discontinuous coating, on the polymer. Because the glass of the present claimed invention is exclusively described in the present application to be formed by a sol gel process in a manner that inherently yields a continuous glass, the discontinuous coating of particles on a substrate of '380 can not anticipate the invention. Applicants respectfully request that claims 11, 12, 17-19, 30, 33, 36 and 37 be allowed.

Examiner states:

9. Claims 11-13,21,22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducheyne et al (USPN 5,676,720 hereafter '720). The claims are drawn to a composite material comprising a bioglass and biologically active agents. The composite is delivered for sustained release profile.

10. The '720 patent teaches a porous bioglass composite comprising calcium and phosphate molecules (abstract) and other compounds (claims). The composite encapsulates an active agent such as a cell on its surface and is implanted allowing for sustained interaction with the defective implant area (col. 8, lin. 44-65). These disclosures render the claims anticipated.

Applicants respectfully disagree that '720, which teaches a "porous glass substrate", anticipates the present claimed invention. The "porous glass substrate" of '720 lacks the polymer of the present invention and is never referred to as a composite within '720 because it is not a composite, rather it is a combination of discrete glass particles connected into a porous substrate. All claims of '720 are directed to the formation of a structure that does not contain a polymer nor is a composite recited; it cannot anticipate a structure that contains a polymer. The method of '720 does not include any composite forming sol-gel processing or any other processing in the presence of a polymer that can form a structural equivalent to the composite of the present invention. Hence, '720, which discloses a porous glass substrate, can not anticipate the composite containing a polymer of the present claimed invention. Applicant respectfully requests that claims 11-13, 21, 22 and 25 be allowed.

Examiner states:

11. Claims 11,20, and 36-38 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Niederauer et al (USPN 6,344,496 hereafter '496). The claims are drawn to a bioglass composite comprising a calcium and phosphate molecule along with other common excipients. The composite has a porosity of at least 50%. The claims further recite a method of making the composite where the temperature is below 200 degrees Celsius and the composition is sprayed or extruded.

12. The '496 patent teaches a bioglass composite comprises a calcium and phosphate bioglass compound (col. 4, lin. 19-38). The composite further comprises polymers known in the art such as polyglycolide and glycolide/lactide copolymers (col. 5, lin. 62-col. 6, lin. 18). The composite is used as an implantable device (col. 6, lin. 49-59). The porosity of the composite is between 60-90 % (col. 8, lin. 5-15). The composite is formed at room temperature and is spray-dried (examples). These disclosures render the claims anticipated.

Applicants respectfully disagree with the conclusion that '496 anticipates the present invention. The '496 teaches the mixing of a polymer with discrete particles of a "bioactive ceramic" to yield a composite. (see title, abstract, all claims, all examples, and throughout the specification) This composite of the present invention is prepared by the dispersion of a polymer with a sol precursor of a bioactive glass. The sol is then gelled into a non-crystalline glass, not a ceramic where crystalline phases exist, to have a co-continuous dispersion of the polymer and continuous inorganic network, the glass. (see paragraph [0060] of the present application) As the present invention involves a continuous glass rather than the discontinuous ceramic of '496, the present invention can not be anticipated by the '496. Applicants respectfully request that claims 11-20 and 36-38 be allowed.

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Applicants have made every effort to present claims which distinguish over the cited art and supported in the specification, and it is believed that all claims are in condition for allowance. However, Applicants invite the Examiner to call the undersigned if it is believed that a telephonic interview (direct line (561) 671-3656) would expedite the prosecution of the application to an allowance. Although no fees are believed to be due, the Commissioner for Patents is hereby authorized to charge any deficiency in fees due with the filing of this document and during prosecution of this application to Deposit Account No. 50-0951.

Respectfully submitted,

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